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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,395

08/22/2007

Guido Grandi

002441.00212

9708

27476

7590

02/26/2009

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

02/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,395	Applicant(s) GRANDI ET AL.	
	Examiner Padma V. Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11, 12, 15, 18, 21, 26, 28, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 21, 26, 28, 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/12/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

1. The amendment filed on 12/1/08 is entered.

Restriction

2. Applicant's states that the lack of unity established by the examiner is improper because accession number does not anticipate the claims.

This is not found persuasive because Accession number E72033 disclose a polypeptide comprising the (680) amino acid sequence, which is 100% identical to the claimed polypeptide SEQ.ID.NO : 55 as discussed below in the action under art rejections. Therefore, only claims 1-4, 15, 18, drawn to product with respect to SEQ.ID.NO: 55 are under examination. The examiner will rejoin the method claims once the product claims 1-4, 15, 18 with respect to SEQ.ID.NO: 55 found allowable.

Status of Claims

3. Claims 1 has been amended.
Claims 5-10, 13-14, 16-17, 19-20, 22 -25, 27 and 29 have been canceled.
Claims 1-4, 11, 12, 15, 18, 21, 26, 28, 30 and 31 are pending.
Claims 11-12, 21, 26, 28 and 30-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention,
Claims 1-4 and 15 and 18 are under examination with respect to SEQ.ID.NO:55.

4. The examiner acknowledges the power of attorney submitted by the applicant on 12/1/08.

Information Disclosure Statement

5. The Information Disclosure Statement filed on 12/12/08 has been reviewed and a signed copy of the same is attached to this office action.

Specification Objection withdrawn

6. In view of amendment to the specification, the objection to the Brief Description of the Drawings is withdrawn.

Claim Rejections - 35 USC 101 withdrawn

7. In view of amendment to claim1, the rejection under 36 U.S.C. 101 is withdrawn.

Art Unit: 1645

Claim Rejections - 35 USC 112, second paragraph withdrawn

8. In view of amendment to claim 1, the rejection under 35 U.S.C. 112, second paragraph, is withdrawn.

Claim Rejections - 35 USC § 102/ 35 USC § 103 maintained

9. The rejections of claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number: E 72033 and claims 1-4 , 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Accession number: E 72033 as applied to claims 1-4 above, and further in view of Probst et al U.S. Patent: 6,432,916 B1 are maintained exactly for the same reasons as set forth in the previous office action.

Applicant argues that 12/1/08 the Office has not shown that the claimed amino acid sequence were publicly available at the time of filing. As a threshold matter (and shown in the attached GenBank printout), Accession No. E72033 was "removed or replaced" and it is not indicated what differences exist as between Accession No. E72033 and the current sequence. What is clear, however, is that the sequence replacing E72033 was not available until January 26, 2006 (see attached IDS), which is after the priority date of the instant application.

Applicant's arguments were fully considered but found to be non-persuasive because as shown in the previous office action and now as shown below Database: PIR, first discloses the sequence under accession number E72033 and is available by 23-Apr-1999. There is no difference between the claimed sequence and the sequence submitted under E72033.

Database: PIR**Entry: E72033****LinkDB:** [E72033](#)**Original site:** [E72033](#)

ENTRY	E72033 #type complete
TITLE	hypothetical protein - Chlamydophila pneumoniae (strain CWL029)
ORGANISM	#formal_name Chlamydophila pneumoniae, Chlamydia pneumoniae
DATE	23-Apr-1999 #sequence_revision 23-Apr-1999 #text_change 09-Jul-2004
ACCESSIONS	E72033
REFERENCE	A72000
#authors	Kalman, S.; Mitchell, W.; Marathe, R.; Lammel, C.; Fan, J.; Olinger, L.; Grimwood, J.; Davis, R.W.; Stephens, R.S.
#journal	Nature Genet. (1999) 21:385-389
#title	Comparative genomes of Chlamydia pneumoniae and C. trachomatis.

Art Unit: 1645

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#cross-references MUID:99206606; PMID:10192388
#accession E72033
##status preliminary
##molecule_type DNA
##residues 1-680 ##label ARN
##cross-references UNIPROT:Q9Z7B0; UNIPARC:UPI00000C220D; GB:AE001661;
GB:AE001363; NID:g4377104; PIDN:AAD18934.1; PID:g4377107
##experimental_source strain CWL029
GENETICS
#gene CPn0796
SUMMARY #length 680 #molecular-weight 72143 #checksum 9495
SEQUENCE
      5           10           15           20           25           30
1  M Q P C L N M S I V R N S A L P L P C L S R S E T F K K V R
31 S H M K F M K V L T P W I Y R K D L W V T A F L L T A I P G
61 S F A H T L V D I A G E P R H A A Q A T G V S G D G K I V I
91 G M K V P D D P F A I T V G F Q Y I D G H L Q P L E A V R P
121 Q C S V Y P N G I T P D G T V I V G T N Y A I G M G S V A V
151 K W V N G K V S E L P M L P D T L D S V A S A V S A D G R V
181 I G G N R N I N L G A S V A V K W E D D V I T Q L P S L P D
211 A M N A C V N G I S S D G S I I V G T M V D V S W R N T A V
241 Q W I G D Q L S V I G T L G G T T S V A S A I S T D G T V I
271 V G G S E N A D S Q T H A Y A Y K N G V M S D I G T L G G F
301 Y S L A H A V S S D G S V I V G V S T N S E H R Y H A F Q Y
331 A D G Q M V D L G T L G G P E S Y A Q G V S G D G K V I V G
361 R A Q V P S G D W H A F L C P F Q A P S P A P V H G G S T V
391 V T S Q N P R G M V D I N A T Y S S L K N S Q Q Q L Q R L L
421 I Q H S A K V E S V S S G A P S F T S V K G A I S K Q S P A
451 V Q N D V Q K G T F L S Y R S Q V H G N V Q N Q Q L L T G A
481 F M D W K L A S A P K C G F K V A L H Y G S Q D A L V E R A
511 A L P Y T E Q G L G S S V L S G F G G Q V Q G R Y D F N L G
541 E T V V L Q P F M G I Q V L H L S R E G Y S E K N V R F P V
571 S Y D S V A Y S A A T S F M G A H V F A S L S P K M S T A A
601 T L G V E R D L N S H I D E F K G S V S A M G N F V L E N S
631 T V S V L R P F A S L A M Y Y D V R Q Q Q L V T L S V V M N
661 Q Q P L T G T L S L V S Q S S Y N L S F

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Applicant argues 12/1/08 that E72033 was not available until January 26, 2006 and shows accession number AAD18934.

Applicant's arguments were fully considered but found to be non-persuasive because the examiner as indicated below the cross-reference for E72033 is UNIPROT:Q9Z7B0. The history of this sequence indicates (see reference cited on form 892 attached with PDF) that the sequence version has not been changed (see Q9Z7B0 history 1) but the text version has changes several times including the date cited by applicant January 2006 (see text version 23 in the attached Q9Z7B0 history 2). Therefore, E72033 is available as of 1999.

For applicant's convenience the examiner searched the accession number E72033 on database Genbank and found that it is available as accession number AAD18934, in which the sequence version has not changed but the text is replaced as shown in the attached PDF file refereed as AAD

Art Unit: 1645

18934 history. Applicant did not show that the sequence version has been replaced as of Jan 2006 and is different from that of the E72033.

ACCESSION Q9Z7B0
VERSION Q9Z7B0 GI:81789924
DBSOURCE UniProtKB: locus Q9Z7B0_CHLPN, accession Q9Z7B0;
class: preliminary.
extra accessions: Q7AI98, Q7BWY4
created: May 1, 1999.
sequence updated: May 1, 1999.
annotation updated: Oct 31, 2006.
xrefs: AE001363.1, AAD18934.1, BA000008.3, BAA99004.1,
AE017159.1,
AAP98754.1, B86590, E72033
xrefs (non-sequence databases): GenomeReviews:AE009440_GR,
GenomeReviews:BA000008_GR, GenomeReviews:AE001363_GR,
KEGG:cpj:CPj0796, KEGG:cpn:CPn0796, KEGG:cpt:CpB0825,
BioCyc:CPNE115713:CPN0796-MONOMER,
BioCyc:CPNE138677:CPJ0796-MONOMER,
BioCyc:CPNE182082:CPB0825-MONOMER, InterPro:IPR005546,
Pfam:PF03797
KEYWORDS Complete proteome; Hypothetical protein.
SOURCE Chlamydophila pneumoniae
ORGANISM Chlamydophila pneumoniae
Bacteria; Chlamydiae; Chlamydiales; Chlamydiaceae; Chlamydophila.
REFERENCE 1 (residues 1 to 680)
AUTHORS Kalman, S., Mitchell, W., Marathe, R., Lammel, C., Fan, J.,
Hyman, R.W.,
Olinger, L., Grimwood, J., Davis, R.W. and Stephens, R.S.
TITLE Comparative genomes of Chlamydia pneumoniae and C. trachomatis
JOURNAL Nat. Genet. 21 (4), 385-389 (1999)
PUBMED 10192388
REMARK NUCLEOTIDE SEQUENCE [LARGE SCALE GENOMIC DNA].
STRAIN=CWL029
REFERENCE 2 (residues 1 to 680)
AUTHORS Shirai, M., Hirakawa, H., Kimoto, M., Tabuchi, M., Kishi, F.,
Ouchi, K.,
Shiba, T., Ishii, K., Hattori, M., Kuhara, S. and Nakazawa, T.
TITLE Comparison of whole genome sequences of Chlamydia pneumoniae J138
from Japan and CWL029 from USA
JOURNAL Nucleic Acids Res. 28 (12), 2311-2314 (2000)
PUBMED 10871362
REMARK NUCLEOTIDE SEQUENCE [LARGE SCALE GENOMIC DNA].
STRAIN=J138
REFERENCE 3 (residues 1 to 680)
AUTHORS Geng, M.M., Schuhmacher, A., Muehldorfer, I., Bensch, K.W.,
Schaefer, K.P., Schneider, S., Pohl, T., Essig, A., Marre, R. and
Melchers, K.
TITLE Direct Submission
JOURNAL Submitted (??-MAY-2002)
REMARK NUCLEOTIDE SEQUENCE [LARGE SCALE GENOMIC DNA].
STRAIN=TW-183

Art Unit: 1645

COMMENT On or before Nov 11, 2005 this sequence version replaced
 gi:25356869, gi:7468344.

FEATURES Location/Qualifiers

source	1..680	/organism="Chlamydophila pneumoniae"
		/db_xref="taxon:83558"
gene	1..680	
		/locus_tag="CPj0796"
		/gene_synonym="CpB0825"
		/gene_synonym="CPn_0796"
Protein	1..680	
		/locus_tag="CPj0796"
		/gene_synonym="CpB0825"
		/gene_synonym="CPn_0796"
		/product="Hypothetical protein"
Region	9..377	
		/locus_tag="CPj0796"
		/gene_synonym="CpB0825"
		/gene_synonym="CPn_0796"
		/region_name="COG5563"
		/note="Predicted integral membrane proteins containing uncharacterized repeats [Function unknown]; COG5563"
		/db_xref="CDD:35122"
Region	<465..624	
		/locus_tag="CPj0796"
		/gene_synonym="CpB0825"
		/gene_synonym="CPn_0796"
		/region_name="Autotransporter"
		/note="Autotransporter beta-domain; cl02365"
		/db_xref="CDD:121263"

ORIGIN

```

1  mqpclnmsiv  rnsalplpcl  srsetfkkvr  shmkmkvlt  pwiyrkdllw  taflltaipg
61  sfahtlvdia  geprrhaaqt  gvsgdgkivi  gmkvpddpfa  itvgfqyidg  hlqpleavrp
121 qcsvypngit  pdgtvivgtg  yaimgsvav  kwvngkysel  pmlpdtldsv  asavsadgrv
181 iggnrninlg  asvavkwedd  vitqlpslpd  amnacvngis  sdgsiivgtm  vdvswrntav
241 qwigdqlsvi  gtlggtsva  saistdgtvi  vggssenadsq  thayaykngv  msdigtlggf
301 yslahavssd  gsvivgvstn  sehryhafqy  adgqmvdlgt  lggpesyaqg  vsgdgkvivg
361 raqvpsgdwh  aflcpfqaps  papvhggstv  vtsqnprgmv  dinatysslk  nsqqqlqrll
421 iqhsakvesv  ssgapsftsv  kgaiskqspa  vqndvqkgtf  lsyrsvhgn  vqnqqlltga
481 fmdwklasap  kcgfkvalhy  gsqdalvera  alpyteqglg  ssvlsgfggq  vggrydfnlg
541 etvvlqpimg  iqvlhlsreg  yseknvrfpv  sydsveysaa  tsfmgahvfa  slspkmstaa
601 tlgverdlns  hidefkgsvs  amgnfvlns  tvsvlrpfas  lamyydvrrq  qlvtlsvmn
661 qqpltgtlsl  vsqssynlsf

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Conclusion

10. Claims 1-4 and 15 and 18 are rejected.

This application contains claims 11-12, 21, 26, 28 and 30-31 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Art Unit: 1645

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert B. Mondesi on 571- 272-0956.

Respectfully,
/Padma Baskar/
Examiner 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645